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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,290	10/15/2003	Ivan Osorio	011738.00134	8970
22908	7590	09/13/2007		
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			EXAMINER HOLMES, REX R	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/687,290

Applicant(s)

OSORIO ET AL.

Examiner

Rex Holmes

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-21, 23, 28, 29, 32, 37, 38 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21, 23, 28-29, 32, 37-38, 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Pat. 6,128,538 hereinafter "Fischell") in view of Chen et al. (U.S. Pat. 6,618,617 hereinafter "Chen").

5. In reference to claims 1-2, 6, 8, 13-15, 19-20, 28-29, 37-38, 43-46, Fischell discloses method for treating neurological disorders utilizing an implantable therapy

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element that is coupled to an implantable monitoring element (Fig.2, Elements 30, 40).

Fischell further discloses that electrodes for sensing and stimulation are connected to the monitoring and therapy elements and a processor (Col. 2, ll. 63-67 & Col. 3., ll. 1-8, Fig. 2), and that the sensing unit monitors EEG activity (Col. 8, ll. 42-45). Fischell also discloses that once a disorder is determined the therapy is activated (Col. 12, ll. 41-54).

6. In reference to claims 3, 16, Fischell discloses the use of an implantable drug delivery system utilizing a catheter as the therapy delivery element, and the sensing unit is comprised of electrode sensors (Col. 25, ll. 53-67 & Col. 26, ll. 1-3).

7. In reference to claims 4-5, 7 and 9, Fishcell discloses that the treatment of neurological diseases such as epilepsy, migraine headaches and Parkinson's disease (Abstract). Fischell further discloses that the use of implanted electrodes to detect the onset of seizures (Col. 2, ll. 41-56).

8. In reference to claim 10, 23, Fischell discloses that once a event is detected a timer starts to allow the device to determine if enough events occur to limit the number of false positives (Col. 19, ll. 13-46).

9. In reference to claims 17 and 18, Fischell discloses that the device could contain an external control system (Fig. 24; Col. 32, ll. 4-15).

10. Fischell discloses the claimed invention except for the preventing of therapy for a predetermined quantity of block counts after the therapy is activated. Chen discloses an implantable device that has a delay after the initiation of the therapy to allow the user to prepare for therapy or mitigate the discomfort. Chen teaches that it is known to delay therapy as set forth in Column 3, lines 8-16 to provide the patient with time to prepare

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for the therapy or to mitigate the discomfort by allowing the patient to take analgesics or a sedative before the stimulation is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurological stimulator as taught by Fischell, with delay as taught by Chen, since such a modification would provide the neurological stimulator with a delay for providing the patient with time to prepare for the therapy or to mitigate the discomfort by allowing the patient to take analgesics or a sedative before the stimulation is delivered.

11. Similarly, Fischell discloses a neurological stimulator. Chen discloses a delay for therapy for a implantable device that allows the patient time to prepare for the therapy or to mitigate the discomfort by allowing the patient to take analgesics or a sedative before the stimulation is delivered. Fischell in view of Chen provides the predictable result of a neurological stimulator with a stimulation delay timer to allow the patient time to prepare for the therapy or to mitigate the discomfort by allowing the patient to take analgesics or a sedative before the stimulation is delivered.

12. It is noted that block counts are described in the Applicant's specification in paragraph 138 as occurring at a fixed rate of 48 milliseconds. Thus, block counts are a fixed unit of time and a quantity of block counts is equivalent to a period of time.

13. In regards to claim 11 & 21, the Fischell in view of Chen teaches the claimed invention but does not disclose expressly the 30-minute time frame. It would have been an obvious matter of choice to a person of ordinary skill in the art to modify the neurostimulation device as taught by Fischell in view of Chen with a time frame in which the device can acquire data after implantation, because the applicant has not disclosed

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that the 30- minute time frame provides an advantage, is used for a particular purpose, or solves a stated problem by stating that "the time period is a function of the background window length and may vary in duration" (see paragraph. [137] of applicant's disclosure). One of ordinary skill in the art furthermore would have expected applicant's invention to perform equally as well in conjunction with the Fischell in view of Chen neurostimulator because it provides a timeframe in which the Fischell in view of Chen device can acquire data after implantation to allow for the determination of proper stimulation parameters and since it appears to be an arbitrary design consideration which fails to patentably distinguish over the Fischell in view of Chen system. Therefore it would have been obvious matter of design choice to modify the Fischell in view of Chen system to obtain the invention specified in the aforementioned claims.

14. In regards to claim 32, the Fischell in view of Chen teaches the claimed invention but does not disclose an error handling procedure for parameters based on inputted data. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy system as taught by Fischell in view of Chen, with user configurable data and error handling since it was known in the art that when configuration data is calculated and entered either automatically or manually into a medical device that error handling is used to provide a fail safe so that the patient and device are not harmed.

15. In further reference to claim 32, Fischell in view of Chen also teaches the claimed invention except for range of 1 second to 24 hours. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy

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system as taught by Fischell in view of Chen, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes  
Examiner  
Art Unit 3762



George Evanisko  
Primary Examiner  
Art Unit 3762

9/7/11